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APPLICATION NO.	FILING DATE	APP. NAME/INVENTOR	ATTORNEY/AGENT	CLASS
09/804,733	03/13/2001	Qi Wang	MLA 06/14/01	2-4

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EXAMINER

KRUSE, DAVID H

ART UNIT

CLASSIFICATION

DATE MAILED 04/03/2003

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,733

Applicant(s)

WANG ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-19, drawn to a method for producing a recombinant protein containing two tandem repeat units in a bacterial cell, classified in class 435, subclass 69.1, for example.
 - II. Claims 1-19, drawn to a method for producing a recombinant protein containing two tandem repeat units in a yeast cell, classified in class 435, subclass 69.1, for example.
 - III. Claims 1-19, drawn to a method for producing a recombinant protein containing two tandem repeat units in an insect cell, classified in class 435, subclass 69.1, for example.
 - IV. Claims 1-19, drawn to a method for producing a recombinant protein containing two tandem repeat units in an animal cell, classified in class 435, subclass 69.1, for example.
 - V. Claims 1-18 and 20, drawn to a method for producing a recombinant protein containing two tandem repeat units in a plant cell, classified in class 435, subclass 69.1.
 - VI. Claims 21-26, drawn to a plant comprising a transformed plant host cell or a seed of said plant comprising a vector comprising a polynucleotide encoding a recombinant protein containing two tandem repeat units, classified in class 435, subclass 419, for example.

Art Unit: 1638

- VII. Claims 27-44, drawn to a method for producing a recombinant protein containing two adjacent tandem repeat units in a bacterium cell, classified in class 435, subclass 69.1.
- VIII. Claims 27-44, drawn to a method for producing a recombinant protein containing two adjacent tandem repeat units in a yeast cell, classified in class 435, subclass 69.1.
- IX. Claims 27-44, drawn to a method for producing a recombinant protein containing two adjacent tandem repeat units in an insect cell, classified in class 435, subclass 69.1.
- X. Claims 27-44, drawn to a method for producing a recombinant protein containing two adjacent tandem repeat units in an animal cell, classified in class 435, subclass 69.1.
- XI. Claims 27-43 and 45, drawn to a method for producing a recombinant protein containing two adjacent tandem repeat units in a plant cell, classified in class 435, subclass 69.1.
- XII. Claims 46-51, drawn to a plant comprising a transformed plant host cell or a seed of said plant comprising a vector comprising a polynucleotide encoding a recombinant protein containing two adjacent tandem repeat units, classified in class 435, subclass 419, for example.
- XIII. Claims 52-57, drawn to a method for producing a polynucleotide containing at least two tandem repeat units, classified in class 435, subclass 6, for example.

Art Unit: 1638

- XIV. Claims 58-62, drawn to a method for producing a polynucleotide containing at least two adjacent tandem repeat units, classified in class 435, subclass 6, for example.
- XV. Claims 63-83, drawn to a recombinant protein comprising at least two tandem repeats of an amino acid sequence produced in a bacterial cell, classified in class 530, subclass 350, for example.
- XVI. Claims 63-83, drawn to a recombinant protein comprising at least two tandem repeats of an amino acid sequence produced in a yeast cell, classified in class 530, subclass 350, for example.
- XVII. Claims 63-83, drawn to a recombinant protein comprising at least two tandem repeats of an amino acid sequence produced in an insect cell, classified in class 530, subclass 350, for example.
- XVIII. Claims 63-83, drawn to a recombinant protein comprising at least two tandem repeats of an amino acid sequence produced in an animal cell, classified in class 530, subclass 350, for example.
- XIX. Claims 63-82 and 84, drawn to a recombinant protein comprising at least two tandem repeats of an amino acid sequence produced in a plant cell, classified in class 530, subclass 350, for example.
- XX. Claims 85-104, drawn to a recombinant protein comprising at least two adjacent tandem repeats of an amino acid sequence produced in a bacterial cell, classified in class 530, subclass 350, for example.

Art Unit: 1638

- XXI. Claims 85-104, drawn to a recombinant protein comprising at least two adjacent tandem repeats of an amino acid sequence produced in a yeast cell, classified in class 530, subclass 350, for example.
- XXII. Claims 85-104, drawn to a recombinant protein comprising at least two adjacent tandem repeats of an amino acid sequence produced in an insect cell, classified in class 530, subclass 350, for example.
- XXIII. Claims 85-104, drawn to a recombinant protein comprising at least two adjacent tandem repeats of an amino acid sequence produced in an animal cell, classified in class 530, subclass 350, for example.
- XXIV. Claims 85-103 and 105, drawn to a recombinant protein comprising at least two adjacent tandem repeats of an amino acid sequence produced in a plant cell, classified in class 530, subclass 350, for example.
- XXV. Claims 106-111 and 117, drawn to an isolated polynucleotide comprising at least two repeat units, classified in class 536, subclass 23.1, for example.
- XXVI. Claims 112-116 and 118, drawn to an isolated polynucleotide comprising at least two adjacent repeat units, classified in class 536, subclass 23.1, for example.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

Art Unit: 1638

the instant case the different inventions are unrelated because the method of each of Groups I-V has different starting materials and different end products, for example the suitable vector at step 1(h) would be distinct for each of the groups.

3. Inventions I-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of any one of Groups I-IV is not capable of producing the plant of Group VI.

4. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant comprising a transformed plant host cell of Group VI can be made using a materially different process than that of Group V, such as synthesizing a vector encoding a recombinant protein containing two tandem repeat units and transforming a plant.

5. Inventions I-VI and VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of any one of Groups I-IV has different starting materials and different end products than any one of the methods of Groups VII-XI. In addition, the plant comprising a

Art Unit: 1638

transformed host cell of Group VI cannot be made using the method of any of Groups VII-XI.

6. Inventions I-VI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because none of the methods of Groups I-V are capable of making the plant comprising a transformed host cell of Group XII. In addition, the plant comprising a transformed host cell of Group VI is compositionally and functionally distinct from the plant comprising a transformed host cell of Group XII.

7. Inventions I-VI and XIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of any one of Groups I-V has different method steps, different starting materials and different end products than either of Groups XII or XIV. In addition, the plant comprising a transformed host cell of Group VI cannot be made using the method of either Group XII or XIV.

8. Inventions I and XV; II and XVI; III and XVII; IV and XVIII; and V and XIX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

Art Unit: 1638

made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins of Groups XV-XIX can be made using a materially different process, such as synthesizing a vector encoding a recombinant protein containing two tandem repeat units and transforming the respective host cell, or by chemical synthesis.

9. Inventions VI and XV-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant comprising a transformed host cell of Group VI is compositionally, structurally and functionally distinct from the recombinant protein of any of Groups XV-XIX.

10. Inventions I-VI and XX-XXIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because none of the methods of Groups I-V can be used to make the protein of any one of Groups XX-XXIV, and the plant of Group VI is compositionally, structurally and functionally distinct from the protein of any one of Groups XX-XXIV.

11. Inventions I-V and XXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated

Art Unit: 1638

polynucleotide of Group XXV can be used in a materially different process than the method of any one of Groups I-V, such as in a DNA hybridization method.

12. Inventions VI and XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the isolated polynucleotide of Group XXV is compositionally, structurally and functionally distinct from the plant of Group VI.

13. Inventions I-VI and XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the isolated polynucleotide of Group XXVI cannot be made by, or used in the method of any one of Groups I-V. In addition, the plant of Group VI is compositionally, structurally and functionally distinct from the isolated polynucleotide of Group XXVI.

14. Inventions VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of each of Groups VII-XI has different starting materials and different end products, for example the suitable vector at step 1(h) would be distinct for each of the groups.

Art Unit: 1638

15. Inventions VII-X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because none of the methods of Groups VII-X can be used to make the plant comprising a transformed host cell of Group XII.

16. Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant comprising a transformed plant host cell of Group XII can be made using a materially different process than that of Group XI, such as synthesizing a vector encoding a recombinant protein containing two adjacent tandem repeat units and transforming a plant.

17. Inventions VII-XII and XIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of any one of Groups VII-XI has different method steps, different starting materials and different end products than either the method of Group XIII or Group XIV. In addition, the plant comprising a transformed plant host cell of Group XII cannot be made using the method of either Group XIII or Group XIV.

Art Unit: 1638

18. Inventions VII-XII and XV-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are unrelated because the methods of Groups VII-XI cannot be used to make the recombinant protein of any one of Groups XV-XIX. In addition, the plant comprising a transformed host cell of Group XII is compositionally, structurally and functionally distinct from the recombinant protein of any one of Groups XV-XIX.

19. Inventions VII and XX; VIII and XXI; IX and XXII; X and XXIII, and XI and XXIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the proteins of Groups XV-XIX can be made using a materially different process, such as synthesizing a vector encoding a recombinant protein containing two adjacent tandem repeat units and transforming the respective host cell, or by chemical synthesis.

20. Inventions VII-XII and XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the methods of Groups VII-XI cannot be used to make the isolated polynucleotide of Group XXV and

Art Unit: 1638

the plant comprising a transformed host cell of Group XII is compositionally, structurally and functionally distinct from the isolated polynucleotide of Group XXV.

21. Inventions VII-XI and XXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated polynucleotide of Group XXVI can be used in a materially different process than the method of any one of Groups VII-XI, such as in a DNA hybridization method.

22. Inventions XII and XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the plant comprising a transformed host cell of Group XII is compositionally, structurally and functionally distinct from the isolated polynucleotide of Group XXVI.

23. Inventions XIII and XIV and XV-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of either XIII or XIV cannot be used to produce the recombinant protein of any of Groups XV-XXIII.

Art Unit: 1638

24. Inventions XIII and XXV are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the isolated polynucleotide of Group XXV can be made by a materially different process than that of Group XIII, such as by chemical synthesis.

25. Inventions XIII and XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group XIII cannot be used to make the isolated polynucleotide of Group XXVI.

26. Inventions XIV and XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group XIV cannot be used to make the isolated polynucleotide of Group XXV.

27. Inventions XIV and XXVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

Art Unit: 1638

(MPEP § 806.05(f)). In the instant case the isolated polynucleotide of Group XXVI can be made using a materially different process, such as chemical synthesis.

28. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and because the search required for one of the groups is not required for another, restriction for examination purposes as indicated is proper.

29. Applicant is advised that the reply to this requirement to be complete within one month (not less than 30 days) must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

30. In addition, **Applicant is required to elect** one encoded repeat (e.g. SEQ ID Nos. 1 or 2) to be examined in conjunction with the elected group of claims. The Patent and Trademark Office recently published its policy for the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR § 1.141. In establishing the new policy, the Commissioner has partially waived the requirements of 37 CFR § 1.141et seq. and permits a reasonable number of such nucleotide sequences

Art Unit: 1638

to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. The Official Gazette Notice of November 19, 1996 is one that permits the examiner to waive restriction to no more than one invention. Since 1996, databases and resource allocations at the PTO have changed and the examination of 10 sequences on the merits in the instant application would present a burden on PTO resources. Additionally, it is noted that one nucleotide and one amino acid sequence is within the O.G. notice range of "up to ten" sequences. This election is not to be construed as an election of species.

31. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1638

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
24 March 2003

AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600